REMARKS

Claims 1-13 are pending. Claims 10-13 are allowed. Claims 1-9 are rejected. Claims 14-16 have been added.

Claims 1-4 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,388,076 to Waters. Applicant traverses the rejection.

Waters describes a stylet 24 having a steel wire body 26, the distal end 28 of which is formed into a ball. Col. 2, lines 15-27. The proximal end 32 of the wire 26 is formed into a hook, which engages the inside wall 34 of a hollow plug 36 that has been placed inside a connector 38. Col. 2, lines 15-30. The stylet 24 does not comprise a solid, semi-rigid rod. The stylet 24 comprises a wire 26. Wires are pliable. The wire 26 is not secured to the distal end of the connector 38. Rather, the wire 26 is secured by a pressed fit inside a luer connector 6, which is secured to the proximal end 8 of a flexible tube 4 of the intubating device 2 that is described.

Claim 1 is directed to an endotracheal tube retainer comprising "a solid, semi-rigid stylet rod having proximal and distal ends; and a connection adapter tapered from a proximal end of said connection adapter to a distal end of said connection adapter for secure insertion within a range of endotracheal tubes, said adapter being secured to said distal end of said stylet rod."

Waters does not anticipate claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California,* 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Here it is clear that each and every element is not set forth in Waters. Claim 1 is directed to an endotracheal tube retainer that comprises a solid, semi-rigid stylet rod. The device of Waters does not comprise a rod. With reference to Figures 1-5, Waters describes a

device that includes a tube 4, that has a wire 26 inside. Further, Waters does not describe a device that comprises a connection adapter that is secured to the distal end of a solid, stylet rod. The wire 26 described in Waters engages the inside wall 34 of a hollow plug 36 that has been placed inside of a connector 38. Since Waters fails to describe an endotracheal tube retainer comprising "a solid, semi-rigid stylet rod having proximal and distal ends; and a connection adapter tapered from a proximal end of said connection adapter to a distal end of said connection adapter for secure insertion within a range of endotracheal tubes, said adapter being secured to said distal end of said stylet rod" it is respectfully submitted that Claim 1 is not anticipated by Waters. Therefore, Applicant requests that the rejection of Claim 1 under 35 U.S.C. §102 (b) be withdrawn.

Claims 2-4 depend from Claim 1, and therefore, incorporate all of the subject matter of Claim 1. Since it is submitted for the aforementioned reasons that Claim 1 is patentable over Waters, it is likewise submitted that Claims 2-4 are patentable over Waters for the same reasons. Therefore, it is respectfully requested that the rejection of Claims 2-4 under 35 U.S.C. §102(b) be withdrawn.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,582,056 to McCorkle Jr. Applicant traverses the rejection.

McCorkle Jr. describes an endocardial lead extraction device that comprises flexible stainless steel stylet wires 9A that are connected to a screw tip 33. Col. 7, lines 40-44; Col. 8, lines 7-16. The wires 9A are adapted to fit within the inner channel 14 of the catheter 1, which is of slightly larger outside diameter than the insulating sheath of the endocardial lead 11 that is to be removed. Figure 1 and 3; Col. 8, lines 7-33; and Figures 8A-8C. The screw-tip 33 that is

attached to the end of the stylet wire 9A is adapted to engage the free end of the endocardial lead 11 that is to be removed to draw it into the chamber 14 of the catheter 1. McCorkle Jr. does not describe an *endo-tracheal tube* retainer that comprises a semi-rigid stylet rod that is secured to a connection adapter.

McCorkle Jr. does not anticipate claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Here, it is clear that each and every element is not set forth in McCorkle Jr. First, Claim 1 is directed to an endotracheal tube retainer that comprises a solid, semi-rigid stylet rod. The device of McCorkle Jr. does not comprise a solid, semi-rigid stylet rod that is suitable for use as an endotracheal tube retainer. McCorkle Jr. describes an endocardial lead extraction device that comprises stylet wires 9A that are connected to a screw tip 33. Col. 7, lines 40-44; Col. 8, lines 7-16; and Figures 8A-8C. The screw-tip 33 that is attached to the end of the stylet wires 9A is adapted to engage the free end of the endocardial lead 11 that is to be removed to draw it into the chamber 14 of the catheter 1. Col. 8, lines 7-21. The stylet wires 9A of McCorkle are inherently too small to act as endotracheal tube retaining elements. Endotracheal leads are less than 2-3 millimeters in diameter. The wires 9A are adapted to fit within the inner channel 14 of a catheter 1, which is of slightly larger outside diameter than the insulating sheath of the endocardial lead 11 that is to be removed. Figure 1 and 3; Col. 8, lines 7-33. With specific reference to Figures 8A-8C, the screw-tip 33 described must have a diameter that is less than about 2-3 millimeters in order to facilitate engagement with the endocardial lead 11 that is to be removed. Figures 8A-8C. The stylet wires 9A, therefore, must inherently be smaller than

about 2-3 millimeters to allow engagement and removal of the lead 11. The rod of the invention is inherently larger than the stylet wires 9A described in McCorkle because standard endotracheal tubes have diameters that are much greater than the diameters of endocardial leads. In fact use of the stylet wires 9A in the retainer of the invention would render the claimed invention inoperable. The stylet wires 9A are simply to small to engage even the smallest endotracheal tubes. Since McCorkle Jr. fails to describe an endotracheal tube retainer comprising "a solid, semi-rigid stylet rod having proximal and distal ends; and a connection adapter tapered from a proximal end of said connection adapter to a distal end of said connection adapter for secure insertion within a range of endotracheal tubes, said adapter being secured to said distal end of said stylet rod" it is respectfully submitted that Claim 1 is not anticipated by McCorkle Jr. Therefore, Applicant requests that the rejection of Claim 1 as being anticipated by McCorkle Jr. under 35 U.S.C. §102 (b) be withdrawn.

Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Waters. The Examiner argues that Waters teaches *essentially* all of the limitations except for the connection adapter being removably secured to the semi-rigid stylet by means of a threaded connector. The Examiner notes that Applicant has not provided a statement as to how the threaded connector is advantageous over other types of connectors or provides an unexpected result. Applicant traverses the rejection and submits that the Examiner has failed to present a *prima facie* case of obviousness of Claim 5.

To establish a *prima facie* case of obviousness the prior art references when combined must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). There must also be some suggestion or motivation, either in the references

themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In addition, the prior art must provide a reasonable expectation of success for the proposed modification. *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469 (Fed. Cir. 1988). The Examiner has not established a *prima facie* case for obviousness of the laryngeal mask of claim 5.

As stated above, Waters does not teach or suggest all of the claim limitations of Claim 5. Claim 5 depends from Claim 1 and, therefore, includes all of the subject matter of Claim 1. Accordingly, for the same reasons stated above is submitted that all of the limitations of Claim 5 are not taught or suggested by Waters. The Examiner admits that the subject matter of claim 5 is not taught or suggested by Waters. The Examiner argues that Applicant has not provided a statement as to how the threaded connector is advantages over other types of connectors, or evidence of an unexpected result. The Examiner has failed, however, to site any authority for such a requirement. Applicant respectfully submits that there is no requirement that such evidence be submitted and reminds the Examiner that the United States Patent and Trademark Office has the burden to present a *prima facie* case of obviousness prior to the introduction of any rebuttal evidence, if necessary. Here, the Examiner has not met this burden.

There must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. *In re Jones*, 958 F.2d at 347. Here, there is no such suggestion or motivation to modify Waters such that it describes the invention of Claim 5. The deficiencies of references cannot be saved by appeals to common sense and basic knowledge without any

evidentiary support. *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001). Here, the Examiner is applying an "obvious to try" rational, which is clearly improper. *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); *Yamanouchi Pharmaceutical Co. Ltd. V. Marsam Pharmaceuticals, Inc.*, 231 F.3d 1339 (Fed.Cir. 2000).

In addition, Waters must provide a reasonable expectation of success for the proposed modification to render Claim 5 obvious under 35 U.S.C. §103(a). *In re Dow Chemical Co.* F.2d at 469. Here, the Examiner has failed to present evidence that the proposed modification would be successful. Therefore, it is submitted that Claim 5 is patentable over Waters, and Applicant respectfully requests that the rejection of Claim 5 under 35 U.S.C. §103(a) be withdrawn.

Claims 6-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over McCorkle, Jr. in view of U.S. Patent No. 5,579,762 to Lee. Applicant traverses the rejection and submits that the Examiner has again failed to make a *prima facie* case of obviousness of Claims 6-9.

Lee teaches a hollow endotracheal device that comprises an adapter having longitudinal groves. Figure 1. McCorkle Jr. and Claim 1 are described above.

To establish a *prima facie* case of obviousness the prior art references when combined must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). First, even when combined Waters and Lee fail to teach all of the limitations of Claim 1. Claims 6-9 depend from Claim 1, and therefore incorporate all of the subject matter of Claim 1. Lee when combined with Waters does not teach or suggest an endotracheal tube retainer comprising a solid, semi-rigid stylet rod having proximal and distal ends; and a connection adapter tapered from a proximal end of the connection adapter to a distal end of the connection adapter for secure insertion within a range of endotracheal tubes, the adapter being

secured to the distal end of the stylet rod. The device of Lee is hollow. Accordingly, for the same reasons stated above is submitted that all of the limitations of Claims 6-9 are not taught or suggested by Waters, alone, or in combination with Lee.

There must also be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. *In re Jones*, 958 F.2d at 347. Here, there is no such suggestion or motivation to modify Waters such that it describes the invention of Claims 6-9. The deficiencies of references cannot be saved by appeals to common sense and basic knowledge without any evidentiary support. *In re Zurko*, 258 F.3d at 1379. Here, the Examiner is applying an "obvious to try" rational, which is clearly improper. *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999).

In addition, the prior art must provide a reasonable expectation of success for the proposed modification. *In re Dow Chemical Co.*, 837 F.2d at 469. Here, the Examiner has failed to present evidence that the proposed modification would be successful. Therefore, it is submitted that Claims 6-9 is patentable over Waters, and Applicant respectfully requests that the rejection of Claims 6-9 under 35 U.S.C. §103(a) be withdrawn.

Applicant believes that the arguments asserted and the amendments presented herein place all of the pending claims in condition for allowance. If the present amendments and arguments do not place the application in condition for allowance, the Examiner hereby requests a telephonic interview with the Examiner. It is respectfully requested that the Examiner contact the Applicant's undersigned attorney by telephone at (314) 872-8118.

Respectfully submitted,

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